

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v.

BIONPHARMA INC.

Defendant.

C.A. No. 21-1286-MSG

C.A. No. 21-1455-MSG

**DEFENDANT BIONPHARMA'S LETTER REQUESTING LEAVE TO FILE FOR
SUMMARY JUDGMENT BASED ON COLLATERAL ESTOPPEL**

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Defendant Bionpharma requests leave to move for summary judgment solely based on collateral estoppel arising from this Court's decision in the Alkem case¹. D.I.² 268 at 1 n.1.

INTRODUCTION

On February 10, 2023, this Court entered judgment in favor of Alkem and against Azurity based on findings that claims of the '482 and '621 patents³ are invalid for lack of written description and obviousness. Alkem case D.I. 213, Mem. Op.; Alkem case D.I. 214, Order. That judgment ***has preclusive effect now***, irrespective of the appeal Azurity has taken. *Kokinda v. Pa. Dep't of Corr.*, 803 F. App'x 574, 577 (3d Cir. 2020) ("[A] pending appeal does not vitiate the preclusive effect of a trial court judgment."). As explained below, this Court's findings on the issues of written description and obviousness apply equally to the claims of the Third Wave Patents Azurity asserts in the instant suits against Bionpharma ("asserted claims"),⁴ and Azurity is collaterally estopped from relitigating these issues or contesting the invalidity of the asserted claims. There are no material facts in dispute, and Bionpharma should be permitted to move immediately for summary judgment on this estoppel defense.

ARGUMENT

The Federal Circuit looks to regional circuit law in patent cases for general principles on the law of judgments and collateral estoppel. *Intellectual Ventures I LLC v. Cap. One Fin. Corp.*, 937 F.3d 1359, 1370 (Fed. Cir. 2019); *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). A collateral estoppel determination requires proof that: (1) the identical issue was previously litigated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was adequately represented in the previous action. *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006).

I. COLLATERAL ESTOPPEL BARS AZURITY'S PATENT CLAIMS

There can be no dispute that Azurity was adequately represented in the Alkem case, nor that the issues of lack of written description and obviousness were actually litigated there. With respect to the third collateral estoppel factor (necessary to the decision), in the Third Circuit, collateral estoppel applies to alternative grounds underlying a judgment. *Id.* at 255. Thus,

¹ *Azurity Pharm., Inc. v. Alkem Labs. Ltd.*, C.A. No. 19-2100-MSG (D. Del.).

² All docket citations are to the 21-1286 docket unless otherwise specified, all abbreviations not defined herein have meaning ascribed in the Table of Abbreviations set forth in Bionpharma's Stay Motion Reply Br. (D.I. 242), and any quotation emphasis is added unless stated otherwise.

³ The '482 and '621 patents, along with Azurity's '868 patent, are what Bionpharma has referred to in prior briefing as the "Second Wave Patents." Azurity sued Bionpharma for alleged infringement of the Second Wave Patents in late 2020, but that Second Wave Suit was ultimately dismissed because Azurity could not prove infringement. 20-1256 D.I. 49, Second Am. Compl.; 20-1256 D.I. 106, Stipulation of Dismissal; D.I. 152, JSR at 2-3.

⁴ Azurity asserts claims 1-6, 10-16, and 19 of the '023 patent, and claims 1-2, 6-7, 10, 12-14, 17, 19-20, and 22 of the '405 patent. D.I. 264-1, JSS Ex. B-1.

Bionpharma will focus on the first estoppel factor.

A. Identical Issue 1: Whether Stable Paraben-Preserved Enalapril Liquids Are Described in the Common Specification

There can be *no dispute* that the asserted claims cover enalapril liquids preserved with parabens that are stable for at least 12 months at refrigerated conditions. For instance, asserted '023 patent claim 1 (the only independent claim), expressly recites stable enalapril liquids preserved with “sodium benzoate, [or] *a paraben or mixture of parabens.*” D.I. 89-1, First Am. Compl. Ex. A, '023 patent at claim 1. And five (5) of the asserted '023 patent dependent claims narrow the preservative limitation of claim 1 to *expressly require* a paraben or mixture of parabens. *See id.* at claims 13-16, 19. Similarly, the two independent asserted claims of the '405 patent (claims 1 and 13) cover stable enalapril liquids preserved with “...*a paraben, or a mixture of parabens.*” 21-1455 D.I. 1, Compl. Ex. A, '405 patent at claims 1, 13; *see also id.* at asserted claim 19 (preservative limitation narrowed to require a “*paraben or a mixture of parabens.*”).

In the Alkem case, this Court entered judgment in Alkem's favor based on the express finding that the specification of the '482 and '621 patents—which is the same specification for the Third Wave Patents (D.I. 259, Azurity's Answer ¶ 126)—do not describe paraben-preserved enalapril liquids stable for at least 12 months at refrigerated conditions. Alkem case D.I. 213, Mem. Op. at 49-51. *Azurity is estopped from relitigating this finding*, which renders invalid each and every asserted claim. *Ohio Willow*, 735 F.3d at 1342 (“Collateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent.”); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336 (Fed. Cir. 2021) (“[P]atent's written description [must] sufficiently demonstrate[] that the inventors possessed the full scope of the claimed invention.”); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed. Cir. 1998) (“[C]laims may be no broader than the supporting disclosure.”); *Idenix Pharm. LLC v. Gilead Scis., Inc.*, 941 F.3d 1149, 1154-55, 1163-65 (Fed. Cir. 2019) (claims directed to compounds with a methyl group in the 2' up position, and any substituent in the 2' down position invalid because the specification did not describe compounds with a fluorine group in the 2' down position); D.I. 38, Bionpharma's TRO/PI Mot. Opp'n at 18-20.

B. Identical Issue 2: Whether Stable, Buffered, Paraben-Preserved Enalapril Liquids Are Obvious in View of the Prior Art

As a completely independent ground for collateral estoppel, there can be no dispute that the asserted claims cover stable paraben-preserved enalapril liquids that are buffered⁵ and that optionally include flavoring agents and sweeteners—*precisely what this Court found obvious in the Alkem case.* Alkem case D.I. 213 Mem. Op. at 25-45. As an example, claim 18 of the '621 patent, which this Court found obvious, is essentially subsumed within asserted '023 patent claims 1-3, 10, 11, and 13-15, and asserted '405 patent claims 1-2, 12-14, 19, and 22, rendering those claims obvious. “When a patent claims a genus, an invention is obvious if a single embodiment

⁵ While the '023 patent claims do not expressly recite a buffer, Azurity has conceded that they include within their scope buffered enalapril liquids. D.I. 52-5, Reply Buckton Decl. ¶ 18; D.I. 52, Azurity's TRO/PI Reply Br. at 10 n.7 (conceding that Epaned—which includes a citrate buffer (18-1962 D.I. 257, Op. at 6)—is an embodiment of the '023 patent claims).

falling within the scope of the claims is obvious.” *Abbott GmbH v. Centocor Ortho Biotech, Inc.*, 971 F. Supp. 2d 171, 182 (D. Mass. 2013) (citing *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300 (Fed. Cir. 2007)). ***Azurity has repeatedly argued that the claims of the Third Wave Patents are merely broader versions of the ’482 and ’621 patents.*** D.I. 48, Azurity’s First MTD Opp’n 18 (“[A] comparison of the claims of the ’023 Patent against [the claims of the ’482 and ’621 patents] demonstrates that the claims of the ’023 Patent ***are indeed broader.***”); D.I. 238, Azurity’s Stay Mot. Opp’n at 12 (“the claims of the ’405 Patent ***are broader than those*** of the ’023 patent.”). Indeed, Judge Stark expressly found that “it’s undisputed that the ’023 patent,..., contains ***broader claims*** than were asserted in the [First and Second Wave Suits],” D.I. 96, 11/10/21 Hr’g Tr. 114:11-15, and Azurity ***repeatedly cited and relied on that finding***, D.I. 181, Azurity’s Rule 12(c) Mot. Opp’n at 1, 10; D.I. 238, Azurity’s Stay Mot. Opp’n at 11.

Breadth aside, just a cursory review of this Court’s Memorandum Opinion in the Alkem case and the asserted claims here reveals that the Court’s finding that stable, buffered and paraben-preserved enalapril liquids are obvious indisputably applies to and renders obvious the asserted claims here. For example, this Court found obvious in the Alkem case ’621 patent claim 18, which claims enalapril liquids consisting essentially of: (i) 0.6 to about 1.2 mg/ml of enalapril (or salt or solvate); (ii) a buffer to maintain the pH below 4.5 at a concentration of 5-20 mM; (iii) a paraben preservative; (iv) water; optionally a sweetener, flavoring agent, or both, and that are stable at refrigerated conditions for at least 24 months. Alkem case D.I. 213, Mem. Op. at 1, 26; Alkem case D.I. 39-1, First Am. Compl. Ex. G, ’621 patent claim 18. Obvious claim 18 of the ’621 patent indisputably discloses ***each and every limitation*** of asserted ’023 patent claims 1-3, which claim enalapril liquids consisting essentially of: (i) 0.6 to about 1.2 mg/ml of enalapril or a pharmaceutically acceptable salt; (ii) a sweetener; (iii) a preservative that can be a paraben or mixture of parabens; (iv) water; (v) optionally a flavoring agent, and that are stable at refrigerated conditions for at least 12 months (or 18 or 24 months).⁶ D.I. 89-1, ’023 patent at claims. Same for asserted ’405 patent claims 1-2, which claim enalapril liquids consisting essentially of: (i) 0.6 to about 1.2 mg/ml of enalapril or a pharmaceutically acceptable salt; (ii) a preservative that can be a paraben or a mixture of parabens; (iii) water; optionally a buffer to maintain the pH below 4.5, a sweetener, a flavoring agent, or any combination of the foregoing, and that are stable at refrigerated conditions for at least 12 months. 21-1455 D.I. 1-1, ’405 patent at claims.

The other asserted dependent claims add limitations that this Court already found in the prior art and would be obvious to use—e.g., a pH of about 3.3 (for ’023 patent claims 4-5), about 1 mg/mL of a paraben or mixture of parabens (for ’023 patent claims 16 and 19 and asserted ’405 patent claims 10 and 20), about 1 mg/mL of enalapril maleate (for ’023 patent claim 12 and ’405 patent claims 6-7 and 17), and sucralose as a sweetener (for ’023 patent claim 6). Alkem case D.I. 213, Mem. Op. at 22-23, 36-37. Thus, the asserted claims ***indisputably*** cover the very subject matter this Court found obvious in the Alkem case, and Azurity is estopped from relitigating this issue and the invalidity of the asserted claims. *Ohio Willow*, 735 F.3d at 1342 (“Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the issues that were litigated that determines whether collateral estoppel should apply.”).

⁶ Azurity has expressly admitted that the ’023 patent claims are anticipated, or at least rendered obvious by, the claims of the First and Second Wave Patents, which includes the claims from the ’482 and ’621 patents that this Court found obvious. D.I. 96, 11/10/21 Hr’g Tr. 16:8-15, 17:5-12.

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